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April 3, 2003

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, Maryland 20852

Re: Proposed Regulations on Prior Notice of Imported Food Under Public Health Security and Bioterrorism Preparedness and Response Act of 2002, **Docket No. 02N-0278**

The American Chemistry Council (ACC) Biocides Panel (Panel) is submitting these comments on behalf of its 46 member companies. A list of the Panel's members is attached. Panel members are engaged in the manufacture, formulation, distribution and sale of antimicrobial active ingredients and formulated end use products registered and regulated by EPA as pesticides pursuant to the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). Some of these EPA-registered antimicrobial pesticides also are regulated by FDA as food additives pursuant to FFDCA section 409 and others are also regulated by EPA as pesticide chemical residues pursuant to FFDCA section 408. The Panel appreciates this opportunity to comment and urges FDA to consider these comments in its continuing deliberations.

As discussed more fully below, the Panel requests FDA to clarify that this regulation requiring prior notice of import is not applicable to antimicrobial pesticides with FDA and/or EPA approval for food contact use. EPA already requires prior notification of each pesticide import. Of even greater significance, *EPA must explicitly approve each pesticide import prior to its arrival*. FDA's inclusion of antimicrobial pesticides within the scope of this regulation would impose unnecessary burdens on antimicrobial pesticide registrants, but without meaningfully enhancing protection of the food supply.

The regulation proposed to be codified at 21 CFR 1.227 defines "food" as the term is defined in FFDCA section 201(f). The regulation also provides an extensive list of examples of what constitutes food for purposes of this rule. The list includes "additives, including substances that migrate into food from food packaging and other articles that contact food." The inclusion of the term "additives" has the effect of extending the definition of food to "substances, the intended use of which results or may reasonably be expected to result, directly or indirectly, either in their becoming a component of food or otherwise affecting the characteristics of food." 21 CFR § 170.3(e)(1). As a consequence, the proposed regulation, as written, applies to any antimicrobial pesticide that ultimately may contact or be incorporated into an article that contacts food by "indirect" or "secondary direct" means, consistent with existing, explicit FDA and/or EPA approval.

Such substances are not themselves food and are not intended to become part of food. Nonetheless, because some migration to food from their use may occur, FDA regulates food contact uses pursuant to FFDCA section 409 and 21 CFR parts 173 through 178. There are numerous FDA approved food additive uses of antimicrobial pesticides. For example, antimicrobials used in fruit and vegetable rinses in food processing facilities and in beet and cane sugar mills to control pathogenic and spoilage microorganisms are regulated as secondary direct food additives. Antimicrobial slimicides used to



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**02N-0278**

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that may come in contact with food; for example, adhesives in food packaging, paper and packaging coatings, and various polymers (e.g., those used in conveyer belts in food processing facilities, restaurant equipment, dairy and milking equipment) are regulated as indirect food additives. Antimicrobial preservatives are used in these and numerous other manufactured goods and articles, including those that may contact food, to protect the articles from deterioration. Preservation is necessary to extend the useful life of such goods, resulting in significant consumer benefits, economic savings and resource conservation.

EPA regulates antimicrobials intended for use on food-contact hard surfaces as pesticide chemical residues. These antimicrobials are not applied to food. Instead they are used to control pathogenic microorganisms on hard surfaces that contact foods. Prior to 1996 they were regulated by FDA as indirect food additives. They continue to meet the definition of food additive, in that their presence in food would occur only by migration from a treated surface to food. Therefore, it is possible that antimicrobials registered for these uses also could be subject to the regulation.

Ironically, other pesticide chemicals that are applied *directly* to food as it is grown or stored would *not* be subject to the prior notification requirement because their uses do not fall within the definition of food "additive." The Panel does not believe that FDA intended its proposal to create this incongruous result.

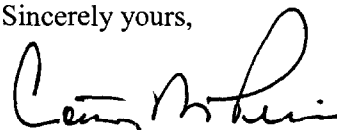
Including antimicrobial pesticides within the scope of this proposal is not only inappropriate, but also unnecessary. Pesticides are imported pursuant to FIFRA, not FFDCA. All pesticide imports, including antimicrobial pesticides, are subject to *prior approval* by EPA before they are admitted to the US. Each importer must submit EPA Form No 3540-1, Notice of Arrival of Pesticides and Devices (NOA), to EPA prior to arrival of the pesticide shipment and *obtain EPA's explicit approval for such import*. 19 CFR 12.112. U.S. Customs may not grant entry unless the importer or agent presents the NOA that has been signed as approved by the EPA Regional official with responsibility for the particular port of entry *and* the Customs officer has confirmed that the shipment is consistent with the EPA NOA form. A copy of the NOA form and instructions for completion is attached.

In conclusion, the Panel requests that FDA clarify that this regulation requiring prior notice of import is not applicable to antimicrobial pesticides with FDA and/or EPA approved food contact uses. Such regulation is unnecessary. EPA stringently regulates antimicrobial pesticide imports, and explicitly approves each shipment prior to its entry to the US. FDA's inclusion of antimicrobial pesticides within the scope of this regulation would impose unnecessary burdens on antimicrobial pesticide registrants without enhancing protection of the food supply.

If you have any questions regarding these comments or related issues, please do not hesitate to Dr. Hasmukh C. Shah of my staff at 703-741-5637.

Attachment

Sincerely yours,



Courtney M. Price  
Vice President, CHEMSTAR

cc: Stuart Shapiro (OMB)